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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Steven D. Jensen and Dan E. Fischer, D.D.S.)	
)	
)	Art Unit
Serial No.	Not Yet Assigned)	1619
)	
Filed:	November 9, 2000)	
)	
For:	COMPOSITIONS AND METHODS FOR WHITENING AND DESSENSITIZING TEETH)	
)	
Examiner:	Raj Bawa, Ph.D.)	

Box: PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

TRANSMITTAL FOR CIP PATENT APPLICATION

Sir:

Transmitted herewith for filing under 37 C.F.R. § 1.53(b) is a patent application which is a continuation-in-part (CIP) of copending prior application Serial No. 09/694,516; which is a continuation-in-part (CIP) of copending prior application Serial No. 09/190,709; the present application which is also a continuation-in-part (CIP) of copending prior application Serial No. 19/494,113.

The present application is entitled COMPOSITIONS AND METHODS FOR WHITENING AND DESENSITIZING TEETH and is filed in the name of the following inventor(s): Steven D. Jensen and Dan E. Fischer, D.D.S.

Enclosed are the following:

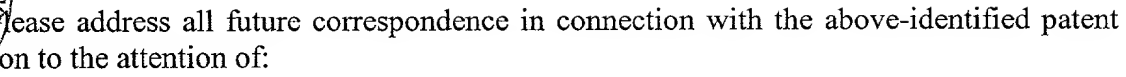
- X A specification, claims, abstract, and cover page in total comprising thirty-seven (37) pages.
- X Five (5) sheets of formal drawings.
- X A joint signature Declaration, Power of Attorney and Petition.
- X An Assignment conveying the invention to Ultradent Products, Inc., including a Form PTO-1595 recordation cover sheet.
- X A Certificate of Mailing by "Express Mail" certifying a filing date by use of Express Mail Label No. EL675130955US.
- X Priority to United States Patent Application Serial Nos. 09/694,516, 09/190,709 and 09/494,113 is claimed under 35 U.S.C. § 120.

The filing fee has been calculated as shown below.


			SMALL ENTITY		LARGE ENTITY	
FOR	NO. FILED	NO. EXTRA	RATE	FEE	RATE	FEE
BASIC FEE				\$355		\$710.00
TOT. CLAIMS	20 -20=	0	X 9=	0	X 18=	
IND. CLAIMS	3 -3=	0	X 40	0	X 80=	
MULTIPLE DEPENDENT CLAIM			+135=	0	+270=	
			TOTAL		TOTAL	\$710.00

- X Check No. 118108 in the amount of \$710.00 is enclosed to cover the filing fee.
- X Check No. 118561 in the amount of \$40.00 is enclosed to cover the recordation fee for the enclosed assignment.
- X The Commissioner is hereby authorized to charge payment of or credit any overpayment of fees to Deposit Account No. 23-3178. A duplicate copy of this letter is enclosed.

Page 3



Dated this 10th day of November 2000.


John M. Guynn

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EXPRESS MAIL LABEL NO. EL675130955US

PATENT APPLICATION
Docket: 7678.350.2

UNITED STATES PATENT APPLICATION

of

Steven D. Jensen

and

Dan E. Fischer, D.D.S.

for

**COMPOSITIONS AND METHODS FOR WHITENING
AND DESENSITIZING TEETH**

WORKMAN, NYDEGGER & SEELEY

A PROFESSIONAL CORPORATION

ATTORNEYS AT LAW
1000 EAGLE GATE TOWER
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The compositions are preferably used with a dental tray that is thin-walled, flexible and lightweight. Preferred dental trays should be adapted for maximum comfort and will exert little, if any, significant mechanical pressure onto the person's teeth or gums. When using a tray of this nature, the tooth whitening compositions of the present invention will preferably be sufficiently sticky, viscous and resistant to dilution by saliva so as to act as a glue-like material and reliably adhere and retain the dental tray over the person's teeth for a desired time duration. Although such dental trays are preferred, any conventional dental trays may also be utilized. The inventive dental compositions may also be applied directly to a person's teeth without using a tray. In such cases, higher concentrations of the active bleaching agents will preferably be used in order to speed up the desired bleaching action.

Any component other than the active dental agents, such as the potassium nitrate, bleaching agent, antimicrobial agent and anticariogenic agent, shall comprise the “carrier”. In the case where the dental composition is sticky and viscous, the carrier will constitute a sticky matrix material formed by combining a sufficient quantity of a tackifying agent, such as carboxypolymethylene, with one or more solvents, such as glycerin, polyethylene glycol, or water. Although the carrier is preferably formed by combining a tackifying agent and a solvent, the carrier may comprise a solvent without a tackifying agent in some embodiments. Preferred compositions, as described hereinbelow, are relatively sticky and glue-like to enable a preferred dental tray to be held and retained against a person’s teeth. Preferred carriers are preferably safe for oral use, do not readily dissolve in saliva, and do not react with the tooth opacifying agent.

In addition to carboxypolymethylene, examples of other suitable tackifying agents, or thickening agents that can assist other tackifying agents, include xanthan gum, talha gum, tragacanth gum, carboxymethylcellulose, locust bean gum, guar gum, Irish moss gum, ghatti gum, furcelleran gum, carrageenan gum, arabic gum, alginic acid gum, agar gum, alginate gum, proteins, such as collagen, PEMULEN®, a proprietary compound of B.F. Goodrich,

1 POLYOX®, a mixture of polyethylene oxides having a molecular weight of 100,000-
2 8,000,000 and available from Union Carbide, including higher molecular weight
3 polyethylene glycols, or any compositional or chemical equivalents of the foregoing.
4 PEMULEN® is a propriety formula that includes a significant quantity of a polyacrylic
5 copolymer that has a slightly hydrophobic end and a strongly hydrophilic end.

6 In addition to glycerin, many other polyols may serve as suitable solvents. The
7 solvent may also be water alone or in combination with a polyol. Glycerin is a preferred
8 solvent as it works well in forming a sticky gel with carboxypolymethylene. Glycerin also
9 provides some flavor enhancement. A few possible substitutes for glycerin include
10 propylene glycols, polypropylene glycol, polyethylene glycols, erythritol, sorbitol, mannitol,
11 other polyols, and the like. In some embodiments polyols such as glycerin, lower molecular
12 weight polyethylene glycols, polypropylene glycol, propylene glycol, and sorbitol may also
13 be used without a tackifying agent.

14 As indicated hereinabove, one currently preferred sticky matrix material includes a
15 mixture of carboxypolymethylene together with other suitable admixtures. The term
16 “carboxypolymethylene” is used to denote a broad category of polymers, particularly
17 copolymers of acrylic acid and polyallyl sucrose. Because carboxypolymethylene that has
18 not been completely neutralized includes active carboxylic acid groups or moieties,
19 carboxypolymethylene can be classified as a weak acid. When dispersed in water,
20 carboxypolymethylene can have a pH as low as about 2.5.

21 Because highly acidic compositions can etch teeth, it is generally preferable to adjust
22 the pH of dental compositions that include carboxypolymethylene or other acids to make
23 them less acidic. Accordingly, it is preferable to adjust the pH of the bleaching compositions
24 to within a range from about 4 to about 9, more preferably to within a range from about 5 to
25 about 8. Because it is contemplated that the carboxypolymethylene used in the matrix
26 material and the compositions of the present invention will be mixed with a base to raise the

1 An improved dental tray that is thin-walled, flexible and lightweight for holding the
2 dental composition adjacent to a person's teeth is preferably used in combination with sticky
3 and viscous dental whitening compositions of the present invention. The general process for
4 preparing such dental trays is as follows. First, an alginate impression which registers all
5 teeth surfaces plus the gingival margin is made and a stone cast is made of the impression.
6 Optional reservoirs can be prepared by building a layer of rigid material on the stone cast on
7 specific teeth surfaces to be treated. A dental tray is then vacuum formed from the modified
8 cast using a thin, flexible plastic sheet material. Once formed, the tray is preferably trimmed
9 barely shy of the gingival margin on both the buccal and lingual surfaces of the person's
10 teeth. The resulting tray provides a comfortable fit of the person's teeth, with optional
11 reservoirs or spaces located where the rigid material was placed on the stone cast. The trays
12 can optionally overlap the gums if desired to provide contact between the dental
13 compositions and a person's gums. The trays of the present invention have greatly increased
14 comfort and exert little or no significant mechanical pressure on a person's teeth or gums.
15 Instead, sticky dental compositions within the scope of the invention can act like a glue to
16 hold the improved trays in place.

17 The amount of tooth whitening obtained through the use of the inventive
18 compositions and methods is dependent primarily upon (1) the length of time each day the
19 tray is worn; and (2) the number of days the tray is worn. The treatment schedule may be
20 tailored to each person's lifestyle or response to the treatment and can be performed as often
21 as a person desires to provide effective relief from excessively translucent teeth. It has been
22 found that treatment during sleep is a good treatment period since there is less mouth activity
23 which causes less whitening composition to be pumped from the tray.

24 In short, the desensitizing bleaching compositions according to the invention include
25 a dental bleaching agent (*e.g.*, carbamide peroxide) in an amount so as to effect bleaching of
26 a person's teeth, typically by maintaining the dental composition in contact with the person's

1 teeth for at least about 15 minutes, more preferably for at least about 1 hour. They also
2 include potassium nitrate in an amount so as to both reduce sensitivity that may be caused
3 by contacting the dental bleaching agent with a person's teeth and also to enhance the
4 whitening effect of the dental bleaching agent. By means of a comparative study discussed
5 below, the inventors discovered the surprising and unexpected result that the desensitization
6 and enhanced whitening properties of potassium nitrate are actually higher when included
7 in lower concentrations (*e.g.*, 0.5%) rather than at higher concentrations (*e.g.*, 3%).

8 Moreover, the compositions of the present invention should be contrasted with
9 conventional desensitizing tooth paste compositions formulated with large quantities of
10 abrasives (*e.g.*, 20% or more by weight) and high concentrations of potassium nitrate (*e.g.*,
11 up 10% by weight) which are intended to contact the teeth during daily brushing (typically
12 for 60 seconds or less). Such compositions are formulated to treat past, rather than
13 prospective, tooth sensitivity. They do not treat sensitivity caused by simultaneous contact
14 of the teeth with a dental bleaching agent, particularly since no significant bleaching and
15 sensitization of a person's teeth are likely using peroxide-containing toothpastes due to the
16 extremely short contact times.

17 Accordingly, an object of the present invention is to provide improved compositions
18 and methods for whitening teeth, including compositions and methods for opacifying
19 excessively translucent teeth.

20 It is another object to provide compositions for whitening and opacifying teeth
21 which reduce tooth sensitivity compared to conventional dental bleaching compositions.

22 These and other objects and features of the present invention will become more fully
23 apparent from the description as follows, or may be learned by the practice of the invention.
24

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a stone cast of a person's teeth with a coating being applied to selected teeth surfaces.

Figure 2 is a perspective view of the stone cast of Figure 1 with a dental tray formed from the cast and trimmed below the gingival margin.

Figure 3 is a cross-sectional view taken along line 3-3 of Figure 2.

Figure 3A is an enlarged close-up view taken within the section line 3A-3A of Figure 3.

Figure 4 is a cross-sectional view taken along line 4-4 of Figure 2.

Figure 5 is a perspective view of the opacifying composition being delivered from a syringe into a thin-walled, flexible dental tray.

Figure 6 is a perspective view of a thin-walled, flexible dental tray filled with the opacifying composition just before being positioned on a person's upper arch.

Figure 7 is a perspective view of a thin-walled, flexible dental tray filled with the opacifying composition positioned on a person's upper arch.

1 whitening composition that can itself act as an adhesive in holding a comfortable, non-self-
2 retaining dental tray against a person's teeth. The use of carboxypolymethylene, either alone
3 or in combination with other tackifying agents, eliminates the need to use dental trays that
4 are self-retaining (*i.e.*, typically trays that are rigid, which mechanically interlock over a
5 person's teeth or gums, and which are intended for use with less sticky compositions).

6 Carboxypolymethylene is a broad term that refers to vinyl polymers having active
7 carboxyl groups. Suitable carboxypolymethylene compositions may be obtained from B. F.
8 Goodrich Company under the trade name CARBOPOL®. Another tradename for
9 carboxypolymethylene is CARBOMER®. In a commonly-sold form, carboxypolymethylene
10 can have a pH as low as 2.5. As discussed below, the pH of compositions made with
11 carboxypolymethylene can be raised to yield compositions that are less acidic.

12 One currently preferred carboxypolymethylene resin is known by the tradename
13 CARBOPOL 934P. CARBOPOL 934P is a high purity pharmaceutical grade of
14 CARBOPOL 934, having an approximate molecular weight of about 3,000,000. In addition
15 to thickening and suspending, CARBOPOL 934P has been used in dry tablets to impart
16 sustained release properties. Extensive toxicity studies have been conducted on
17 CARBOPOL 934P, and a master file has been established with the Food and Drug
18 Administration. It is listed as CARBOMER 934P in the National Formulary. A more
19 recently preferred carboxypolymethylene is CARBOPOL 974P NF, which has more recently
20 surpassed CARBOPOL 934P as the carboxypolymethylene of choice. Although
21 CARBOPOL 974P NF is similar or identical in molecular weight compared to CARBOPOL
22 934P, it is purified in a way that makes it more pharmaceutically acceptable material.

23 It is believed that other carboxypolymethylene resins, such as CARBOPOL 940, may
24 be substituted for CARBOPOL 934P or CARBOPOL 974P NF. CARBOPOL 934P and
25 CARBOPOL 974P NF are currently preferred because they are obtainable in a
26 pharmaceutical grade.

1 The amount of carboxypolymethylene within the inventive dental whitening
2 compositions can vary depending on the desired level of stickiness and also the identities and
3 amounts of the other components within the dental composition. In general, the dental
4 whitening/desensitizing compositions of the present invention will preferably include
5 carboxypolymethylene in a concentration in a range from about 0.5% to about 25% by weight
6 of the dental whitening composition, more preferably in a range from about 2% to about 12%
7 and most preferably in a range from about 3% to about 10%. Where is it desired to increase
8 the stickiness, viscosity and resistance to dilution to saliva, one may adjust the concentration
9 of carboxypolymethylene to achieve a desired level of any or all of these properties.
10 Increased stickiness assists in retaining the preferred dental trays against a person's teeth.
11 Alternatively, compositions can be made less adhesive and tacky if desired, particularly is
12 applied directly without a dental tray.

13 It should be understood, however, that the actual amount of carboxypolymethylene
14 is not critical for obtaining a sticky, viscous dental composition. For example, the sticky
15 matrix material may include other tackifying components that in combination with, or in lieu
16 of some or all of, the carboxypolymethylene will yield a dental whitening composition
17 having the desired level of stickiness needed to hold a preferred, comfortable-fitting dental
18 tray in place over a person's teeth. Other synthetic polymers and/or natural gums, proteins,
19 or other gel-forming admixtures can be used so long as they yield a sticky dental whitening
20 composition.

21 In order to obtain good dispersion of the carboxypolymethylene resin within the
22 dental whitening composition, it is recommended that the carboxypolymethylene be mixed
23 with a suitable solvent before attempting to add other components that are less compatible
24 with carboxypolymethylene, such as water. Examples of suitable solvents for use with
25 carboxypolymethylene include glycerin, polyalkylene glycols, other polyols, and the like.
26 Glycerin appears to enable larger quantities of carboxypolymethylene to be dispersed in

1 water. It is preferable that the concentration of glycerin, polyol, or like substance utilized as
2 a solvent in the dental whitening compositions be added in a range from about 15% to about
3 85% by weight of the dental whitening compositions, more preferably in a range from about
4 25% to about 75% by weight, and most preferably in a range from about 30% to about 65%
5 by weight.

6 Glycerin, other polyols, and the like are inexpensive solvents that work well in
7 forming a sticky gel with carboxypolymethylene. The glycerin also provides some flavor
8 enhancement such that a bland, sweet flavor is perceived. A few possible substitutes for
9 glycerin include propylene glycol, polypropylene glycol, polyethylene glycols, sorbitol,
10 mannitol, erythritol, other polyols, stearyl alcohol and other alcohols, and the like. Ethylene
11 glycol would also work but is disfavored since it is toxic. In addition to acting as a solvent
12 for the tackifying and thickening agents, hydrophilic solvents such as glycerin, polyethylene
13 glycols, polypropylene glycol, propylene glycol, and sorbitol may also be used as a suitable
14 carrier without a tackifying agent.

15 Water may also be included as a solvent within the compositions of the present
16 invention, although more carboxypolymethylene or other tackifying agent must generally be
17 included as more water is included in order to maintain the same level of stickiness. The
18 amount of water included within the dental whitening compositions of the present invention
19 is preferably in a range of about 0% to about 50% by weight of the dental whitening
20 composition, more preferably in a range of about 1% to about 45% by weight and most
21 preferably in a range of about 2% to about 40% by weight. It will be appreciated that the
22 total quantity of water in the dental whitening composition may come from different sources.
23 For instance, some constituents such as dental agents and bases discussed below may come
24 as aqueous solutions.

25 Because carboxypolymethylene is a polycarboxylic acid, it tends to lower the pH of
26 the resulting dental whitening compositions significantly, down to a pH of about 2.5 in some

1 cases. Although measuring the pH in anhydrous compositions is generally meaningless, the
2 theoretical pH becomes relevant when an anhydrous dental composition is applied to a
3 person's teeth, which are bathed in water-containing saliva. It appears, based upon clinical
4 and *in vitro* testing, that dental whitening compositions with a pH below about 5 are able to
5 etch enamel. To avoid etching enamel, it is preferable to add a neutralizing agent, or more
6 specifically, a base in order to raise the pH of the inventive dental whitening compositions
7 to within a pH range of about 4 to about 9, preferably to within a range of about 5 to about
8 8, and most preferably a pH from about 6 to about 7.

9 Inorganic and organic bases may be used to raise the pH, with the use of
10 concentrated aqueous sodium hydroxide (50% NaOH in water) being one currently preferred
11 embodiment. In addition to sodium hydroxides, other inorganic bases may be used such as
12 potassium hydroxide and ammonium hydroxide. Examples of suitable organic bases include
13 alkyl amines such as triethanolamine, di-isopropanol amine and other similar amines. The
14 amount of neutralizing agent or base to be included will generally depend on the desired pH
15 and the amount of carboxypolymethylene in the dental whitening composition. Accordingly,
16 neutralizing agents or bases are preferably included in a range from about 1% to about 12%
17 by weight of the dental whitening composition, more preferably in a range from about 2%
18 to about 8% by weight and most preferably in a range from about 3% to about 7% by weight.

19 The term "carboxypolymethylene" shall be understood to include carboxypoly-
20 methylene resins regardless of the pH of the overall dental composition. In other words, the
21 term "carboxypolymethylene" broadly includes resins that have been mixed with a base to
22 raise the pH of the compositions. Moreover, the term "carboxypolymethylene" shall broadly
23 include carboxypolymethylene resins that have reacted with, formed complexes with, or
24 otherwise been altered in any way by other components within the dental whitening
25 compositions of the present invention so long as the carboxypolymethylene or mixture
26 product thereof is able to impart the desired level of stickiness and viscosity to the final

1 dental whitening composition in combination with the other components within the dental
2 whitening composition.

3 In addition to carboxypolymethylene, examples of other suitable tackifying and
4 thickening agents include gums such as xanthan gum, talha gum, tragacanth gum, locust bean
5 gum, guar gum, Irish moss gum, ghatti gum, furcelleran gum, carrageenan gum, arabic gum,
6 alginic acid gum, agar gum, and alginate gum, as well as proteins, such as collagen, or
7 cellulosic ethers. Another suitable tackifying agent is sold as PEMULEN®, a proprietary
8 compound from B.F. Goodrich, or a compositional or chemical equivalent thereof.
9 PEMULEN® includes a significant quantity of a polyacrylic copolymer that has a slightly
10 hydrophobic end and a strongly hydrophilic end. Additional examples of suitable tackifying
11 agents include polyethylene oxides such as POLYOX® sold by Union Carbide. These
12 tackifying agents may be present in the same ranges as discussed above in relation to
13 carboxypolymethylene.

14 Examples of suitable bleaching agents include aqueous hydrogen peroxide,
15 carbamide peroxide, benzoyl peroxide, glyceryl peroxide, percarbonates and perborates of
16 alkali and alkaline earth metals (*e.g.*, sodium perborate) and peroxyacetic acid. A significant
17 advantage of using potassium nitrate as an opacifying agent in combination with a bleaching
18 agent in a tooth whitening composition is that the potassium nitrate simultaneously decreases
19 the sensitivity of the teeth that may result from the use of the bleaching agent. The bleaching
20 agents are preferably included in a range from about 0.5% to about 50% by weight of the
21 dental whitening composition, more preferably in a range from about 1% to about 30% by
22 weight and most preferably in a range from about 3% to about 20% by weight.

23 In order to preserve the stability of the dental whitening compositions, it is often
24 preferable to include an ion scavenger such as EDTA, salts of EDTA such as edetate
25 disodium, oxine EDTA, calcium disodium EDTA, and others. Additionally, ion scavengers
26 such as citric acid, succinic acid, adipic acid, nitrates and phosphates of tin and any other

1 the stickiness of the dental whitening compositions of the present invention, they should not
2 be taken to be a limitation as to the actual length of time that the patient may wish to use the
3 inventive dental whitening compositions. While a given dental whitening composition may
4 be able to retain the dental tray against a person's teeth for, *e.g.*, 10 hours or more, that
5 composition could certainly be used within the scope of the present invention for any desired
6 time period, such as for 15 minutes, one hour, or any desired time duration.

7 The desensitizing dental whitening compositions of the present invention may be
8 used at any time and for any duration by a person that desires to whiten his or her teeth.
9 Although the dental whitening compositions of the present invention facilitate the use of
10 flexible, thin-walled dental trays that are more comfortable to use compared to prior dental
11 trays, the insertion of any dental tray within a person's mouth will cause some alteration of
12 behavior and diminution of the freedom to use one's mouth. Therefore, in order to maximize
13 treatment time and reduce the inconvenience of having a dental tray lodged within a person's
14 mouth, it is recommended to use the dental trays at night during a person's sleep.

15 It has been found that optimal results are achieved from cyclic exposure periods
16 involving repeated exposures over several days or weeks. For example, the treatment regime
17 may alternatively entail exposure for a period of time such as an hour without further
18 exposure until the subsequent day. For day use, it is recommended that the whitening
19 compositions be applied for about 1 to 3 hours. The length of the treatment period during
20 night use may vary with the sleep pattern of the particular person and may accordingly be
21 between about 5 to 9 hours.

22 In order to more clearly illustrate the parameters of the inventive dental whitening
23 compositions within the scope of the present invention, the following examples are
24 presented. The following examples are intended to be exemplary and should not be viewed
25 as limiting to the scope of the invention.
26

Figure 1 displays 18 small plots arranged in a grid, showing the time course of various physiological and behavioral parameters during a 10-minute period. The parameters are listed on the left side of the grid, and the corresponding plots are shown on the right. The parameters include:

- 1. Heart rate (b/min)
- 2. Blood pressure (mmHg)
- 3. Blood glucose (mg/dl)
- 4. Blood lactate (mmol/l)
- 5. Blood pH
- 6. Blood pO₂ (mmHg)
- 7. Blood pCO₂ (mmHg)
- 8. Blood bicarbonate (mmol/l)
- 9. Blood urea nitrogen (mg/dl)
- 10. Blood creatinine (mg/dl)
- 11. Blood ammonia (mg/dl)
- 12. Blood glucose (mg/dl)
- 13. Blood lactate (mmol/l)
- 14. Blood pH
- 15. Blood pO₂ (mmHg)
- 16. Blood pCO₂ (mmHg)
- 17. Blood bicarbonate (mmol/l)
- 18. Blood urea nitrogen (mg/dl)

Each plot shows a time axis from 0 to 10 minutes and a y-axis for the respective parameter. The plots show various trends, including increases, decreases, and stable values over time.

CARBOPOL 974P NF	6.8%
Glycerin	48.45%
Polyethylene glycol 300	5.5%
Water	20.0%
Sodium hydroxide (50%)	5.4%
KNO ₃	3.0%
Carbamide peroxide	10.5%
Disodium EDTA	0.1%
NaF	0.25%

- Page 25 -

1 EXAMPLE 2

2 A preferred dental whitening composition within the scope of the present invention
3 was made according to the procedure of Example 1, except that the ingredients were
4 combined in the following concentrations by weight percent:

5

6	CARBOPOL 974P NF	6.8%
7	Glycerin	35%
8	Polyethylene glycol 300	5.5%
9	Water	20%
10	Sodium hydroxide (50%)	5.8%
11	KNO ₃	0.5%
12	Carbamide peroxide	10.5%
13	Disodium EDTA	0.3%
14	Peppermint Flavor	0.6%
15	Xylitol	15%

16

17 The resulting dental whitening/desensitizing composition was tested and found to
18 be surprisingly superior to test compositions similar to those of Example 1 that included 3%
19 potassium nitrate. Compared to tooth whitening/desensitizing compositions that included
20 3% potassium nitrate, the 0.5% formulation of Example 2 exhibited greatly reduced tooth
21 sensitivity. These included sensitivity to hot and cold, as well as general sensitivity of gums,
22 tongue and throat. The 0.5% formulation of Example 2 also showed a dramatic increase in
23 tooth whitening ability compared to a test composition that included no potassium nitrate,
24 thus establishing the surprising result that potassium nitrate in minor concentrations greatly
25 increases the whitening effect of the dental bleaching composition.

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Table 1

1	2	3	4	5	6	7	8	9
A	266	37 (13.9)	40 (15)	2 (0.8)	3 (1.1)	14	7	5.4
B	294	51 (17.3)	50 (17)	14 (4.8)	3 (1)	17	6	4.6
C	279	65 (23.3)	45 (16.1)	4 (1.4)	3 (1.1)	17	6	6.7
D	256	61 (23.9)	70 (27.6)	13 (5.1)	2 (0.8)	18	2	7.5
E	216	14 (5.3)	4 (2.1)	0 (0)	0 (0)	7	11	8.6

Column 1 = Composition Tested

Column 2 = Total number of days used by all patients in group

Column 3 = Number of days sensitive to hot or cold (% of total days)

Column 4 = Number of days gums sensitive (% of total days)

Column 5 = Number of days tongue sensitive (% of total days)

Column 6 = Number of days throat sensitive (% of total days)

Column 7 = Number of patients reporting sensitivity to anything

Column 8 = Number of patients reporting no sensitivity to anything

Column 9 = Average number of shade tab changes

As clearly demonstrated by the data set forth in Table 1, the comparative study showed a dramatic decrease for composition E in the number of days that patients experienced hot or cold sensitivity compared compositions A-D. Surprisingly, even though potassium nitrate was heretofore believed to be a desensitizing agent at any concentration, when mixed with a dental bleaching agent at a concentration of 3% (compositions B-D), it actually *increased* patient tooth sensitivity compared to composition A, which included no potassium nitrate. This demonstrated that potassium nitrate, when blended with a dental bleaching agent and used, does not behave as a desensitizing agent but instead increases sensitivity at certain concentrations (e.g. 3%). Even more surprisingly, composition E resulted in an average Vita tab shade change of 8.6, which was even more than any of compositions A-D, including composition D, which included approximately 50% more

at least one of the following thickening agents: xanthan gum, Irish moss gum, ghatti gum, furcelleran gum, carrageenan gum, arabic gum, alginic acid gum, agar gum, alginate gum, a tackifying protein, or a cellulosic ether.

EXAMPLE 14

A dental whitening composition within the scope of the present invention is made according to Example 1, except that the ingredients are combined in the following concentrations by weight percent:

Glycerin	89%
KNO ₃	1%
Carbamide peroxide	15%

The foregoing procedure results in a dental whitening composition having similar opacifying and desensitizing capabilities compared to the composition of Example 2. However, the composition is less sticky than the composition of Example 2 and has greater bleaching capability.

1 13. A dental bleaching composition as defined in claim 1, wherein the dental
2 bleaching agent is included in an amount of about 1% to about 30% by weight of the dental
3 bleaching composition.

14. A dental bleaching composition as defined in claim 1, wherein the dental bleaching agent is included in an amount of about 3% to about 20% by weight of the dental composition.

15. A dental bleaching composition as defined in claim 1, further including a bleaching agent stabilizer that is at least one of EDTA, a salt of EDTA, adipic acid, succinic acid, citric acid, a nitrate of tin, or a phosphate of tin.

13 16. A dental bleaching composition as defined in claim 1, wherein the dental
14 bleaching composition is substantially free of abrasives.

15

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Figure 1 consists of 12 sub-graphs labeled (a) through (l). Each graph plots a physiological parameter against time (0 to 10 minutes). The y-axis for all graphs ranges from 0 to 100. The x-axis for all graphs ranges from 0 to 10 minutes. The graphs show that HR, SV, CO, MAP, PVR, SVR, and PVR/SVR ratio all increase during the intervention period, while PVR (dynes/cm²) and SVR (dynes/cm²) remain relatively stable.

Parameter	Unit	Baseline (0-10 min)	Intervention (10-20 min)
(a) HR	b/min	~70	~85
(b) SV	ml	~50	~60
(c) CO	l/min	~5.0	~6.0
(d) MAP	mmHg	~80	~90
(e) PVR	mmHg	~10	~15
(f) SVR	mmHg	~100	~120
(g) PVR/SVR ratio		~0.1	~0.12
(h) PVR	dynes/cm²	~100	~120
(i) SVR	dynes/cm²	~1000	~1200
(j) PVR/SVR ratio		~0.1	~0.12
(k) PVR	dynes/cm²	~100	~120
(l) SVR	dynes/cm²	~1000	~1200

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1 18. A method for whitening and desensitizing a person's teeth comprising:
2 providing a dental bleaching composition including:
3 a dental bleaching agent included in an amount so as to have a tooth
4 whitening effect when contacted with a person's teeth.
5 potassium nitrate included in an amount of about 0.01% to about 2%
6 by weight of the dental bleaching composition and so as to enhance the tooth
7 whitening effect of the dental bleaching agent and reduce tooth sensitivity
8 that may be caused by the dental bleaching agent; and
9 a carrier into which the dental bleaching agent and potassium nitrate
10 are dispersed; and
11 contacting the person's teeth with the dental bleaching composition for a time
12 period in order that the dental bleaching composition whitens the person's teeth and
13 in order that the potassium nitrate enhances the tooth whitening effect of the dental
14 bleaching agent and reduces tooth sensitivity that may be caused by the dental
15 bleaching agent.

16
17 19. A method for whitening and desensitizing a person's teeth as defined in
18 claim 18, wherein the person's teeth are contacted with the dental bleaching composition for
19 at least about 15 minutes.

20
21 20. A method for whitening and desensitizing a person's teeth as defined in
22 claim 18, wherein the person's teeth are contacted with the dental bleaching composition for
23 at least about 1 hour.
24

ABSTRACT OF THE DISCLOSURE

Composition and methods which include a dental bleaching agent and potassium nitrate for enhanced whitening and reduced tooth sensitivity. The potassium nitrate both enhances the whiteness of teeth beyond the whitening effect of the dental agent and reduces or eliminates tooth sensitivity that would otherwise be caused by the bleaching agent. For prolonged treatment of teeth, lower quantities of potassium nitrate (*e.g.*, 0.5%) have actually been found to work better than larger quantities (*e.g.*, 3%). The dental compositions may be applied directly to the person's teeth, or they may be loaded into a comfortable fitting, flexible, thin-walled dental tray and placed over the person's teeth. In that case, the dental compositions will include a tackifying agent, such as carboxypolymethylene, which assists the composition in retaining the dental tray over the person's teeth as a result of the adhesive properties of the dental composition rather than due to mechanical interlocking of the tray over the person's teeth. The dental compositions may further include anticariogenic and antimicrobial agents.

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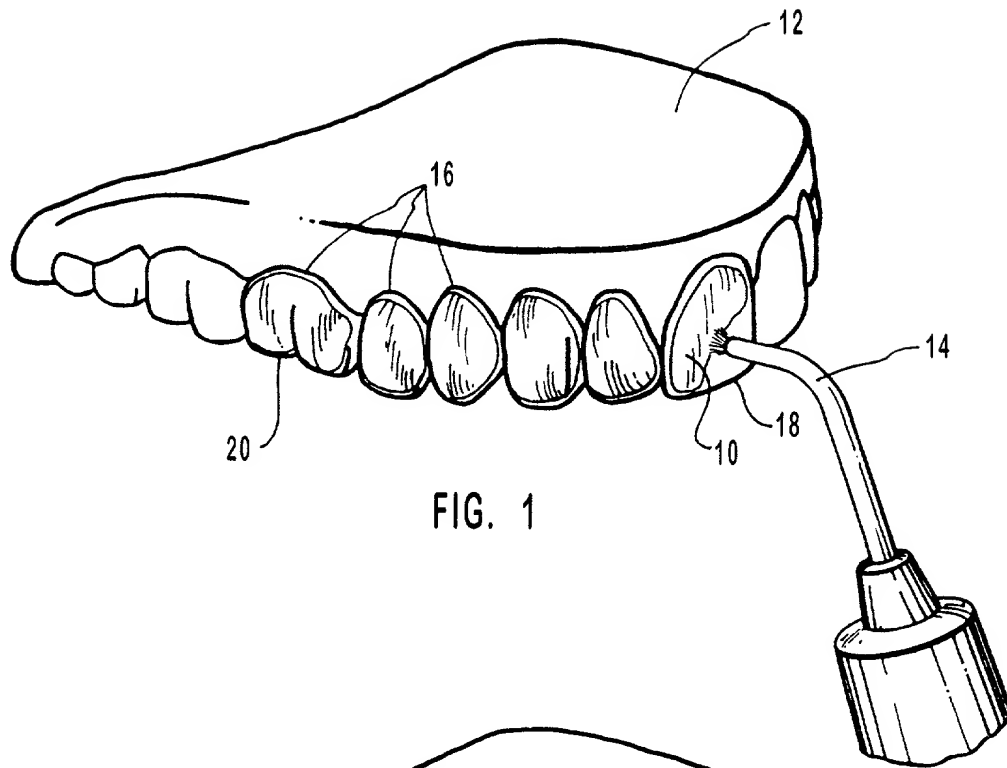


FIG. 1

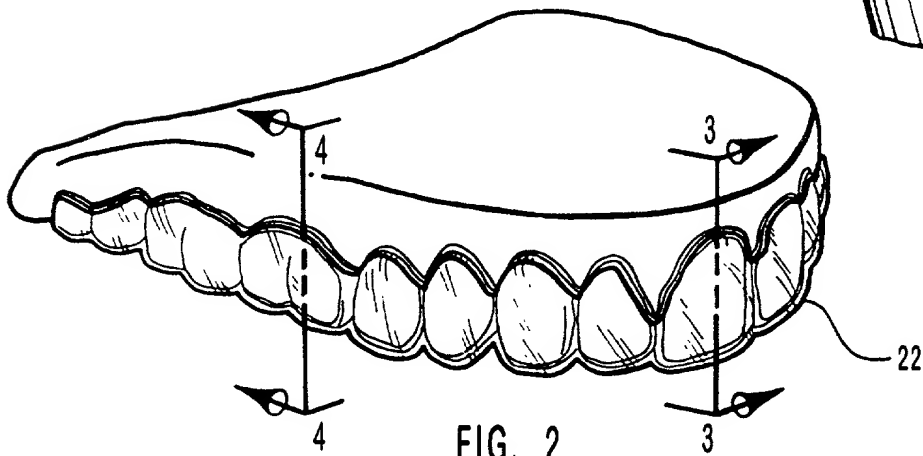


FIG. 2

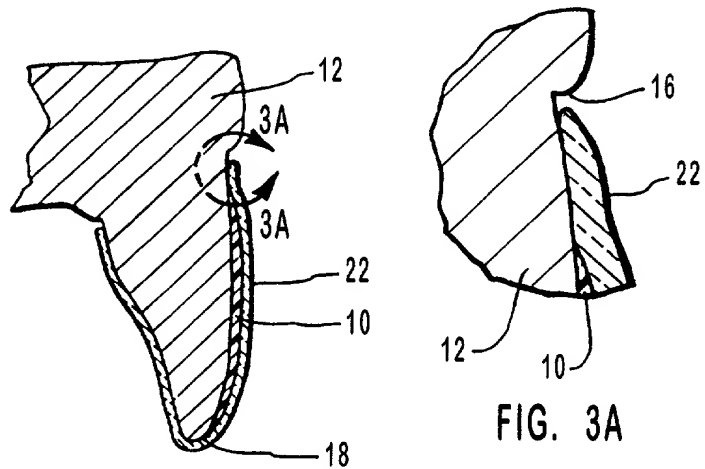
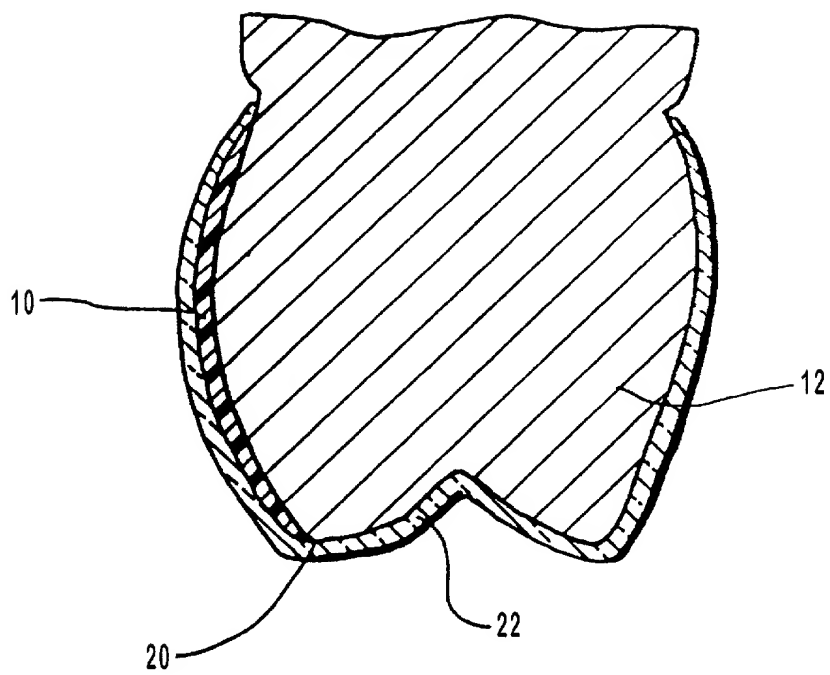


FIG. 3

FIG. 3A



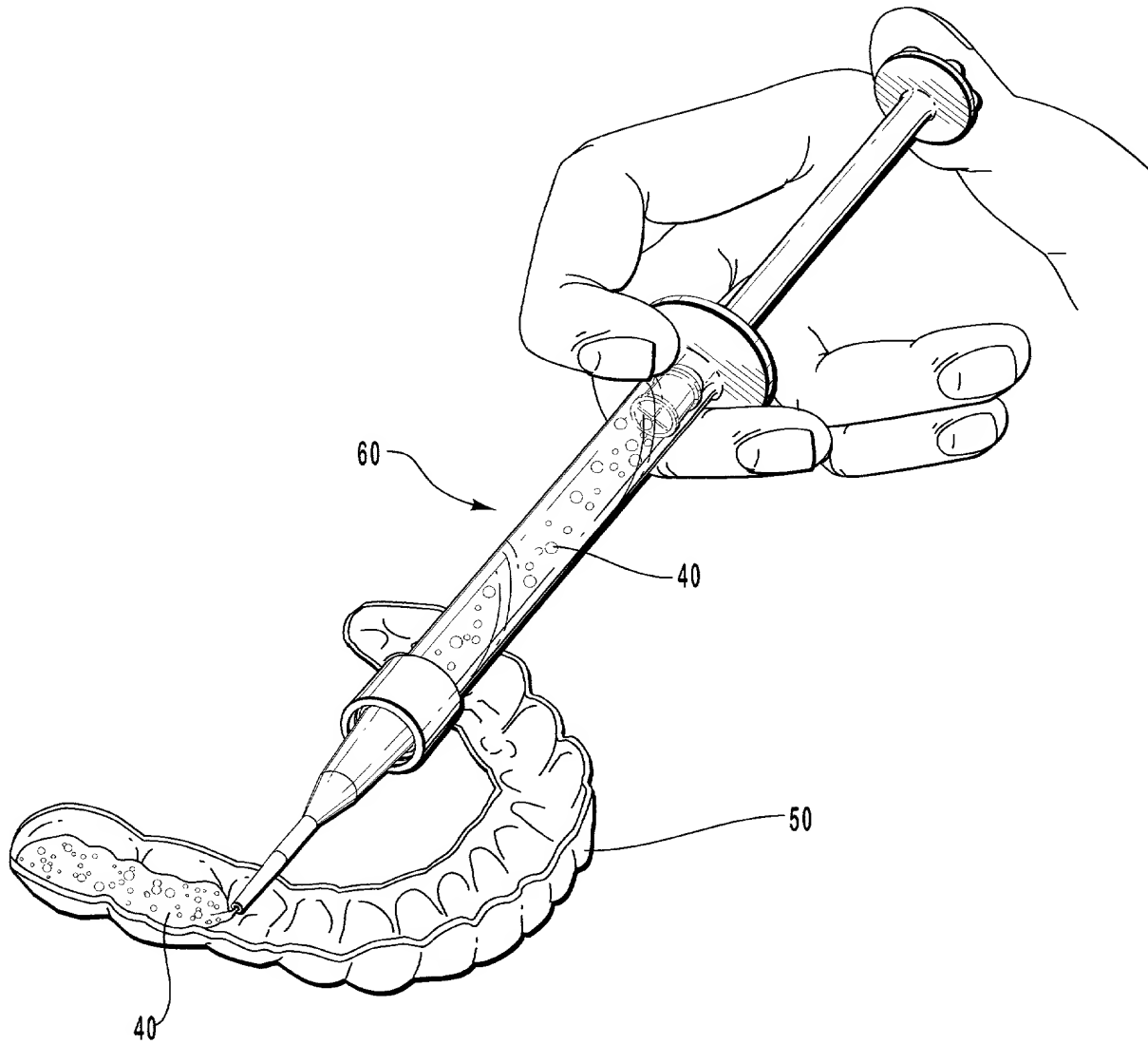
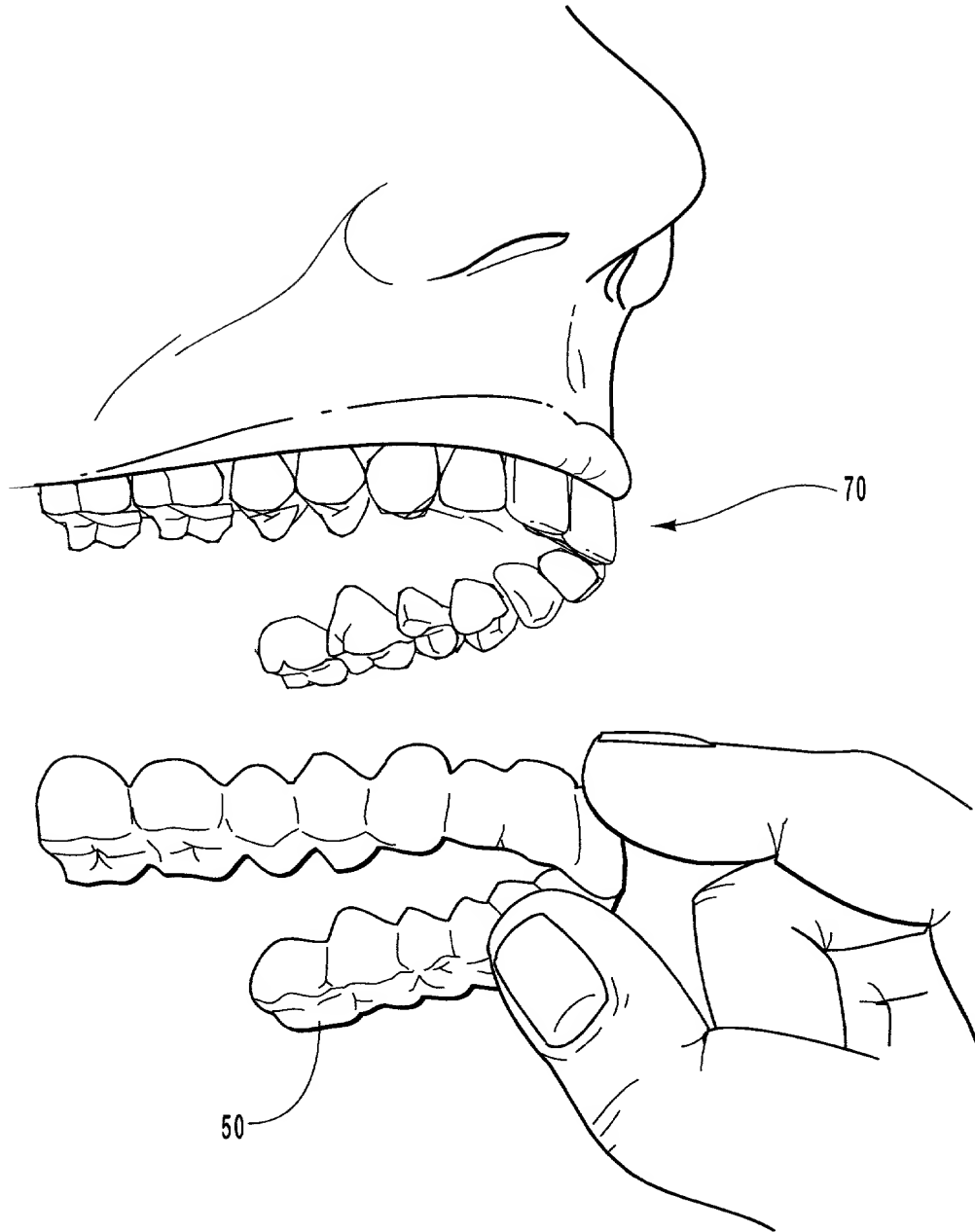


FIG. 5



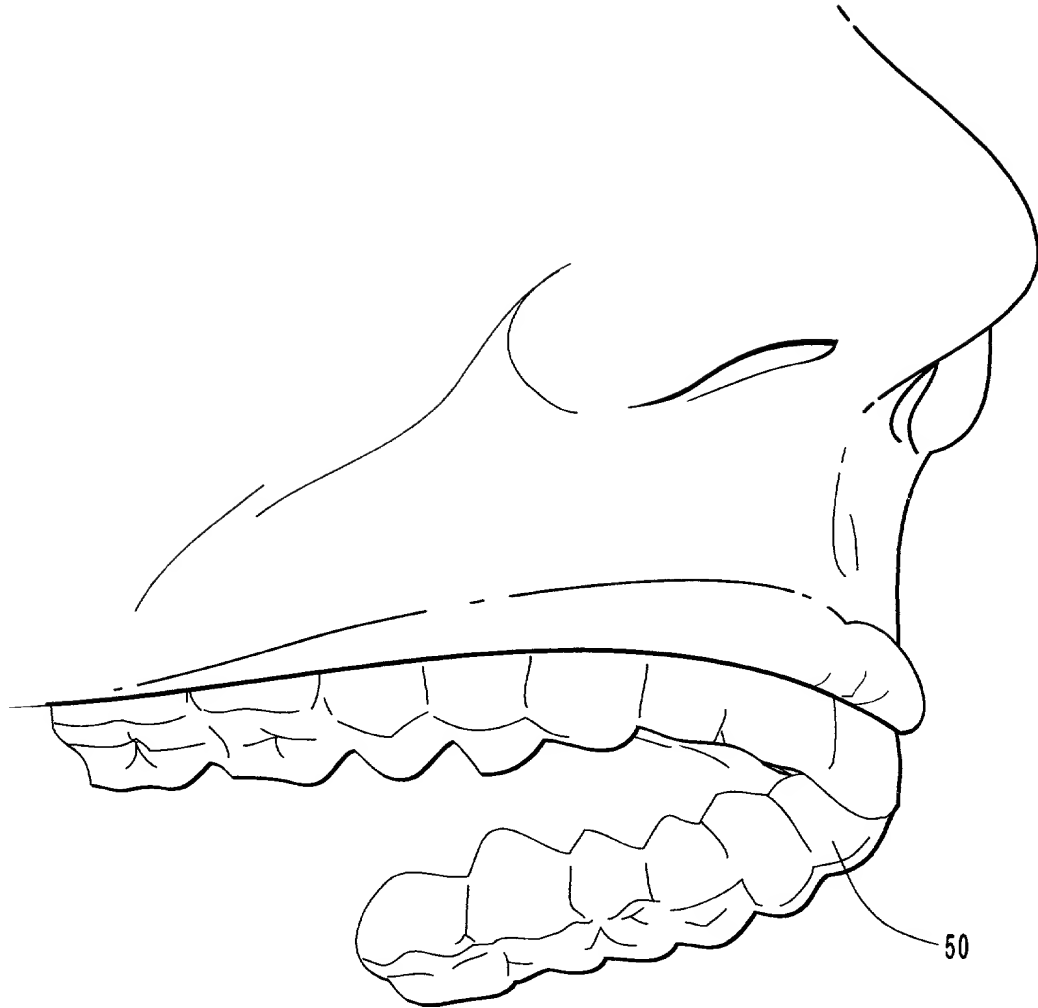


FIG. 7

DECLARATION, POWER OF ATTORNEY, AND PETITION

We, Steven D. Jensen and Dan E. Fischer, D.D.S., declare: that we are citizens of the United States of America; that our residences and post office addresses are 1190 West Chavez Drive, South Jordan, Utah 84095; and 1044 South Dimple Dell Road, Sandy, Utah 84093, respectively; that we verily believe we are the original, first, and joint inventors of the subject matter of the invention or discovery entitled COMPOSITIONS AND METHODS FOR WHITENING AND DESENSITIZING TEETH for which a patent is sought and which is described and claimed in the specification attached hereto; that we have reviewed and understand the contents of the above-identified specification, including the claims referred to, and that we acknowledge the duty to disclose information which is material to the examination of this application in accordance with Section 1.56(a) of Title 37 of the Code of Federal Regulations.

We hereby claim the benefit under Section 120 of Title 35 of the United States Code of the following earlier filed pending applications: Serial No. 09/190,709, filed November 12, 1998 and Serial No. 09/494,113, filed January 31, 2000; and, insofar as the subject matter of each of the claims of this application is not disclosed in the earlier filed pending application in the manner provided by the first paragraph of Section 112 of Title 35 of the United States Code, we acknowledge the duty to disclose material information, as defined in Section 1.56(a) of Title 37 of the Code of Federal Regulations, which occurred between the filing date of the earlier filed application and the filing date of this application.

We declare further that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

We hereby appoint as our attorneys and/or patent agents: RICK D. NYDEGGER, Registration No. 28,651; DAVID O. SEELEY, Registration No. 30,148; JONATHAN W. RICHARDS, Registration No. 29,843; JOHN C. STRINGHAM, Registration No. 40,831; BRADLEY K. DeSANDRO, Registration No. 34,521; JOHN M. GUYNN, Registration No. 36,153; CHARLES L. ROBERTS, Registration No. 32,434; GREGORY M. TAYLOR, Registration No. 34,263; DANA L. TANGREN, Registration No. 37,246; KEVIN B. LAURENCE, Registration No. 38,219; ERIC L. MASCHOFF, Registration No. 36,596; C. J. VEVERKA, Registration No. 40,858; ROBYN L. PHILLIPS, Registration No. 39,330; RICHARD C. GILMORE, Registration No. 37,335; DAVID B. DELLENBACH, Registration No. 39,166; KEVIN K. JOHANSON, Registration No. 38,506; DAVID L. GRIFFIN, Registration No. 44,136; R. BURNS ISRAELEN, Registration No. 42,685; DAVID R. TODD, Registration No. 41,348; FRASER D. ROY, Registration No. P-45,666; CARL T. REED, Registration No. P-45,454; JESÚS JUANÓS i TIMONEDA, Registration No. 43,332; STEPHEN D. PRODNUK, Registration No. 43,020; R. PARRISH FREEMAN, JR., Registration No. 42,556; PETER F. MALEN, JR., Registration No. P-45,576; ADRIAN J. LEE, Registration No. 42,785; KYLE H. FLINDT, Registration No. 42,539; ERIC M. KAMERATH, Registration No. 46,081; and WILLIAM J. ATHAY, Registration No. 44,515, with full power of substitution and revocation, to prosecute this application and to transact

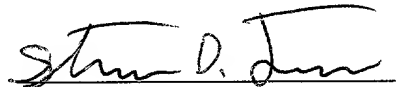
all business in the Patent and Trademark Office connected therewith. All correspondence and telephonic communications should be directed to:

JOHN M. GUYNN
WORKMAN, NYDEGGER & SEELEY
1000 Eagle Gate Tower
60 East South Temple
Salt Lake City, Utah 84111

Wherefore, we pray that Letters Patent be granted to us for the invention or discovery described and claimed in the foregoing specification and claims, declaration, power of attorney, and this petition.

Signed at South Jordan, Utah, this 6th day of November 2000.

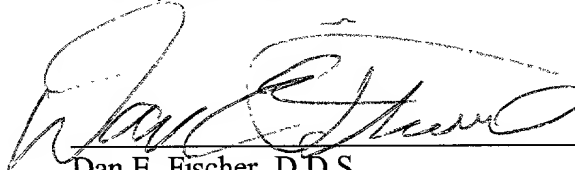
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